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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,399	11/23/2001	George Jackowski	2132.091	4956

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EXAMINER	
TURNER, SHARON L	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,399	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Sharon L. Turner	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 39-46* is/are pending in the application.

4a) Of the above claim(s) *39-46 in part* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 44 in part* is/are rejected.

7)☒ Claim(s) *44-46* is/are objected to.

8)☒ Claim(s) *1 and 39-46* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11-23-01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3-12-02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS 4-21-03*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, now claims 1 and 44 in part to the extent of the peptide consisting of SEQ ID NO:1, in the reply filed on 7-28-05 is acknowledged. The traversal is on the ground(s) that the search for the peptide and methods of use are coextensive. This is not found persuasive because the searches are not coextensive in nature and a reference to one would not necessarily constitute a reference to any other. Rejoinder may only be considered upon indication of allowable subject matter.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 39-43 and 44-46 to the extent of antibody are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7-28-05. It is noted that the antibody is designated as group III as originally set forth.

Specification

3. The disclosure is objected to because of the following informalities: The specification lacks appropriate conformance with the Sequence Rules which require referral to appropriate SEQ ID NO's when referencing amino acid sequences, see in particular p. 46. The Examiner acknowledges proper submissions of CRF and paper copies of the sequence listing.

Appropriate correction is required.

Claim Objections

4. Claim 1 and 44 in part are objected to because of the following informalities: The claim asserts that SEQ ID NO:1 is diagnostic for Alzheimer's disease and that the peptide provides an Alzheimer's diagnostic kit. These recitations are objected to because this use is not evidenced as set forth below. Appropriate correction is required.

Claim Rejections - 35 USC § 101 and 112

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1 and 44 in part are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

8. Claims 1 and 44 in part are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The Examiner acknowledges that the peptide consisting of SEQ ID NO:1 is asserted as being diagnostic for Alzheimer's disease. Diagnosis of Alzheimer's disease

is a specific asserted utility. However, this utility is not specific **and substantial** as a use in diagnosis is not reasonably confirmed.

The specification at p. 46 with reference to Figure 1 asserts that a 15 amino acid portion (SEQ ID O:1) of the full length protein of CENP-E was found to have a molecular weight of 1593.7556 daltons and is related to Alzheimers disease. The specification refers to the evidence as shown in Figure 1. Presumably the figure shows that the peptide consisting of this sequence RHYGETKMNQRSSRS was present in Alzheimer's disease samples in comparison to controls. However, the molecular weight bands of the gel are not visible and moreover the labeling of the figure is inconsistent to show isolation of the 15 mer in disease samples in comparison to controls. In fact the Examiner can find no detailed characterization of the samples that were tested that correspond to Alzheimer's samples, or the methodology used to characterize and/or distinguish Alzheimer's samples from controls. The labeling of the figure is confusing as it identifies both Band 1B and Band 4 as CENP-E. Yet even more confusing is CENP-E is an art recognized protein of over 2600 amino acids in length, see in particular Nature 359:536-39, 1992 corresponding to a molecular weight of over 90 kDa. Accordingly, the specification provides no evidence that the 15-mer is diagnostic to Alzheimer's.

Moreover, the art acknowledges only certain criteria for definitive diagnosis of Alzheimer's Disease, see in particular Gauthier et al., Can. Med. Assoc. J, Oct 15, 1997, 157(8):1047-52, Greicius et al., J Neurol. Neurosurg. Psychiatry, 2002 Jun; 72(6):691-700 and Gasparini et al., FASEB J., 12, Jan. 1998, pp. 17-34. Post mortem analysis of brain tissue for the characteristics of Amyloid plaques is considered

necessary. This is because the art has come to recognize its presence in essentially all cases. However, to achieve diagnostic status took years of evaluative procedures both pre and post mortem confirming that every case has a degree of the pathology. Even so, diagnositic application is often problematic given variable peptide expression patterns amongst clinically similar and dis-similar disease states, see in particular Greicius. In instant case it is not even clear that there is evidence for the presence of the peptide consisting of SEQ IDNO:1 in a single clinically diagnosed Alzheimer's patient as compared to any particular control. No data evidences the short peptides presence amongst others. Accordingly, utility and enablement for the peptide in diagnosis of Alzheimer's Disease is not enabled or established.

The specification is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors relevant to this discussion include the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims. Diagnosis of Alzheimer's disease is no simple matter. No evidence establishes the prevalence of SEQ ID NO:1 in Alzheimer's patients in comparison to control samples. Without such teaching the artisan is not apprised of any use for a peptide consisting of SEQ ID NO:1. It is acknowledged that this is a portion of a mitosis associated peptide. However, no further use or function of the peptide fragment is provided.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). See Ex parte Forman, 230

USPQ 546 (Bd. Pat. App. & Int. 1986). Thus, the skilled artisan cannot readily make and use the claimed invention without further undue experimentation.

Conclusion

9. No claims are allowed.

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Thursday from 7:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached at (571) 272-0867.

Sharon L. Turner, Ph.D.
November 21, 2005

SHARON TURNER, PH.D.
PRIMARY EXAMINER
11-21-05